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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,118	02/18/2004	Marie A. Guion	1004-085US01	1949

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SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER

FLORY, CHRISTOPHER A

ART UNIT PAPER NUMBER

3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/781,118

Applicant(s)

GUION ET AL.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10,12-16,18-20,24,26-38 and 40-58 is/are rejected.
- 7) ☒ Claim(s) 6,9,11,17,21-23,25 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

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Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :07/06/04;
05/23/05; 06/05/06; 07/13/06.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Invention I in the reply filed on 8 November 2006 is acknowledged. The traversal is on the ground(s) that the process as claimed could not be practiced by a materially different apparatus. This is found persuasive because, as stated by Applicant in paragraph 2, the apparatus claims are not limited in their means for providing a diagnostic output, and neither the apparatus nor method claims present a limitation exclusive of the other. Therefore, the requirement for restriction presented in the Office Action filed 10 October 2006 is withdrawn, and all originally filed claims will be considered.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor. A separate listing of the citizenship (e.g. "USA"), not residence, of each inventor is suggested.

Claim Objections

3. Claims 21, 54 and 55 are objected to because of the following informalities:

Claim 21 contains the typographical error "further comprising computing" in the preamble. This should be corrected to read --further comprising ~~computing~~ --.

Claims 54 and 55 both state "The method of claim 53." However, claim 53 is directed to a system/apparatus. To maintain proper dependent form, claims 54 and 55 should be amended to read --The system of claim 53--.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-20 and 36-38 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, but rather merely constitute a recitation of the mathematical process of SVD. Any device that carries out SVD must do so by the steps presented. Mere recitation of a mathematical process or law does not create patentable distinctness, since it does not relate to a practical application thereof or produce a useful, concrete, and tangible result.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 48 is rejected under 35 U.S.C. 102(b) as being anticipated by Hutson (US Patent 5,490,516, hereinafter Hutson'516).

Regarding claim 48, Hutson'516 discloses a diagnostic device (Fig. 1A) comprising a medium that stores data generated by the application of singular value decomposition (hereinafter "SVD") (Fig. 1; ABSTRACT) to digitized representations of auscultatory sounds associated with known physiological conditions (column 5, line 51 through column 6, line 14); and a control unit to output a diagnostic message indicating the selected one of the physiological conditions (Fig. 1, display 4).

Claim Rejections - 35 USC § 103

7. Claims 1-5, 7, 8, 10, 12-16, 18-20, 24, 26, 27, 29, 31, 33-38, 40-47, and 49-58 are rejected under 35 U.S.C. 102(b) as anticipated by Hutson'516 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hutson'516.

Regarding claims 1, 31, 33, 41, 42, 47, 49, 53, 55 and 57, Hutson'516 discloses a method comprising mapping auscultatory sounds to a set of one or more subspaces defined within a multidimensional space (column 3, lines 50-65; column 4, lines 15-20; column 12, lines 32-54), wherein the subspace as disclosed in Hutson'516 is considered equivalent to the disease region as disclosed in the instant Application;

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generating a set of one or more vectors representative of auscultatory sounds (column 5, line 51 through column 6, line 14); and outputting a diagnostic message as a function of the vectors and disease regions (Fig. 1, display 4). Alternatively, if it were not seen that Hutson'516 sufficiently discloses a disease region as defined in paragraph [31] of the instant Application, it would have been obvious to divide the subspaces of Hutson'516 by specific disease since it is the intention of the device to distinguish between diseases and enhance data analysis by means specific to each specific disease.

Further regarding claims 33, 41 and 56, Hutson'516 discloses applying SVD to digitized representations of auscultatory sounds and storing configuration data generated by the application of SVD (Fig. 1; ABSTRACT).

Further regarding claims 53 and 57, Hutson'516 discloses an analysis module (Fig. 1A) and a computer-readable medium (column 10, lines 20-37) for applying the method treated above.

Regarding claims 2, 3, 5, 43, 44, 50 and 58, Hutson'516 discloses selecting one of the disease regions as a function of orientation of the vectors or distance between each of the vectors (column 4, lines 59-67; column 9, line 64 through column 10, line 11; column 12, lines 45-54), wherein characteristics of the auscultatory sounds can include such things as vector orientation and distance in the digital representation of said sounds.

Regarding claim 4, Hutson'516 does not expressly disclose that selecting one of the disease regions comprises selecting the vector having a minimum distance from its

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respective disease region. However, it would have been obvious to select this vector, as closer proximity to the disease region obviously suggests a stronger relationship between a particular vector and that disease than a vector at a farther distance away (which would be related to a different disease or a normal condition). Thus, to say that a disease region is most closely associated with the vector a minimum distance from it is obvious.

Regarding claims 7 and 8, Hutson'516 discloses a diagnostic message identifying one or more specific pathologies experienced by the patient (column 5, lines 50-64) to which the patient is inherently susceptible.

Regarding claim 10, Hutson'516 discloses the message type comprising one of pass/fail, suggested diagnosis, or predictive diagnosis (column 10, lines 40-62).

Regarding claims 12, 34, 45 and 51, and further regarding claim 56, Hutson'516 discloses formulating a set of matrices that store digitized representations of auscultatory sounds and applying SVD to each of the matrices to compute respective sets of sub-matrices that define disease regions (column 3, lines 50-65; column 4, lines 15-20; column 12, lines 32-54).

Regarding claim 13, all matrices can inherently be cited as $N \times M$ matrices, where N and M represent any integer values.

Regarding claim 14, Hutson'516 discloses storing the digitized representations in a raw format (column 6, line 29).

Regarding claims 15 and 35, Hutson'516 discloses storing at least a portion of the sub-matrices within a database for use as configuration data (ABSTRACT).

Regarding claim 16, it is inherent that the data is stored in a format that can be used to compute vectors as it is disclosed that vectors are computed.

Regarding claims 18-20 and 36-38, Hutson'516 inherently discloses each limitation of these claims, as they are merely a recitation of the mathematical process of SVD. Any device that carries out SVD must do so by the steps presented. Mere recitation of a mathematical process or law does not create patentable distinctness, since it does not relate to a practical application thereof or produce a useful, concrete, and tangible result.

Regarding claim 24, Hutson'516 does not explicitly disclose that the sounds are recorded over a plurality of heart cycles, although it does disclose the recording of multiple vectors, which must inherently be based on multiple sounds, and therefore multiple cycles. Furthermore, it would be obvious to carry out the recording of data over multiple heart cycles to provide a means for comparison as required in the Hutson'516 device and method. Merely repeating a step or multiple steps in a previously disclosed process does not distinguish over said prior art.

Regarding claims 26 and 40, Hutson'516 discloses the condition comprising one of a normal physiological condition and stenosis (column 5, lines 50-62).

Regarding claim 27, Hutson'516 discloses capturing the sounds using a first device (Fig. 1A, monitor 8); communicating a digitized representation from a first device to a second device (enhancer 2); analyzing the digitized representation with the second device (enhancer 2); and outputting the diagnostic message with the second device (message sent from enhancer 2 to display 4).

Regarding claims 46 and 54, Hutson'516 discloses that the recordings comprise echocardiograms (column 5, lines 55-58).

Regarding claims 29 and 52, Hutson'516 discloses an echocardiogram analyzer in that Hutson'516 discloses the recordings which are analyzed are echocardiograms.

8. Claims 28, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutson'516 in view of Malilay (US Patent 6,396,931, hereinafter Malilay'931) or in view of Bredesen et al. (US Patent 5,218,969, hereinafter Bredesen'969).

Regarding claims 28, 30, and 32, Hutson'516 discloses the invention substantially as claimed, but does not expressly disclose that the sounds be lung sounds or that the device comprises an electronic stethoscope. In the same field of endeavor, Malilay'931 teaches an electronic stethoscope (Fig. 1) for analyzing lung sounds to reveal and treat various pathological conditions which are detected by through the disruption of normal lung sounds (column 1, lines 10-16 and 45-52). Also in the same field of endeavor, Bredesen'969 teaches an electronic stethoscope (Fig. 1) using matrix analysis of lung sounds (ABSTRACT) to automatically diagnose diseases based on detected abnormal lung sounds. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Hutson'516 with the electronic stethoscope of either Bredesen'969 or Malilay'931 to provide the Hutson'516 system with the same advantage of being used to detect lung sounds for analysis and disease diagnosis and treatment (motivation to combine provided by Malilay'931 column 1, lines 10-16 and 45-52; Bredesen'969 ABSTRACT).

Allowable Subject Matter

9. Claims 6, 9, 11, 17, 21-23, 25 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Flewelling et al. (2004/0209237) and Griffin et al. (2004/0207625) disclose a method and apparatus for displaying diagnostic data comprising mapping of data into disease regions using singular value decomposition, but do not disclose the use of auscultatory sound data associated with known physiological conditions.

Ko (US Patent 6,135,966) discloses a method and apparatus for non-invasive diagnosis of cardiovascular disease and related disorders, but discloses a pressure sensor rather than an auscultatory sound sensor.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

13 December 2006


George Manuel
Primary Examiner